IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Redmon *et al.* Atty Dkt No.: 0701.100E

Serial No.: Continuation of USSN 09/721,088
Filed: November 22 2000
Group Art Unit: 1617
Examiner: Travers, R.

Title: LACTOSE-FREE, NON-HYGROSCOPIC AND ANHYDROUS PHARMACEUTICAL COMPOSITIONS OF DESCARBOETHOXYLORATADINE

Assistant Commissioner for Patents
Box Patent Application
Washington, D.C. 20231

PRELIMINARY AMENDMENT UNDER 37 CFR 1.121(a)

Dear Sir:

Prior to examination of this continuation application, please amend the priority application as follows:

In the specification:

Page 1, delete paragraph 1 (lines 3-6) and replace with:

-- Cross Reference to Related Applications

This application is a continuation of co-pending United States Patent Application Serial Number 09/721,088, filed November 22, 2000 as a continuation of United States Patent Application Serial Number 09/019,955, filed February 6, 1998 and claims priority from United States Provisional Patent Application Serial Numbers 60/053,050 filed July 21, 1997, 60/045,184 filed April 30, 1997, and 60/037,325 filed February 7, 1997. The entire contents of each prior application is incorporated herein by reference. --

In the claims:

Please cancel claims 1-40 and replace with claims 41-60 as shown in the following clean version of pending claims.

Clean version of the pending claims
41-60

41. A pharmaceutical unit dosage form for oral administration, the dosage form comprising a lactose-free core of blended or granulated descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable inert excipients, wherein the core is coated with an inert coating agent.

42. The pharmaceutical unit dosage form of claim 41, wherein the one or more pharmaceutically acceptable inert excipients include one or more wax components.

43. The pharmaceutical unit dosage form of claim 41, wherein the inert coating agent comprises an inert film-forming agent.

44. The pharmaceutical unit dosage form of claim 41, wherein the lactose-free core comprises about 0.1 to 10 mg descarboethoxyloratadine.

45. The pharmaceutical unit dosage form of claim 41, wherein the lactose-free core further comprises an therapeutically effective amount of an analgesic and/or a decongestant.

46. A method of treating histamine-induced disorders, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 41.

47. A method of treating diabetic retinopathy, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 41.

48. A method of treating symptomatic dermographism or dermatitis, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 41.

49. A pharmaceutical unit dosage form for oral administration, the dosage form comprising an anhydrous core of blended or granulated descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable inert excipients, wherein the core is coated with an inert coating agent.

50. The pharmaceutical unit dosage form of claim 49, wherein the lactose-free core comprises about 0.1 to 10 mg descarboethoxyloratadine.

51. The pharmaceutical unit dosage form of claim 49, wherein the lactose-free core further comprises an therapeutically effective amount of an analgesic and/or a decongestant.

52. A method of treating histamine-induced disorders, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 49.

53. A method of treating diabetic retinopathy, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 49.

54. A method of treating symptomatic dermographism or dermatitis, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 49.

55. A pharmaceutical unit dosage form for oral administration, the dosage form comprising a substantially non-hygroscopic core of blended or granulated descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable inert excipients, wherein the core is coated with an inert coating agent.

56. The pharmaceutical unit dosage form of claim 55, wherein the lactose-free core comprises about 0.1 to 10 mg descarboethoxyloratadine.

57. The pharmaceutical unit dosage form of claim 55, wherein the lactose-free core further comprises an therapeutically effective amount of an analgesic and/or a decongestant.

58. A method of treating histamine-induced disorders, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 55.

59. A method of treating diabetic retinopathy, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 55.

60. A method of treating symptomatic dermographism or dermatitis, comprising administering to a person in need of such therapy, a pharmaceutical unit dosage form according to claim 55.

Text showing changes made

In the specification:

Page 1, paragraph 2, is amended:

Cross Reference to Related Applications

This application **is a continuation of co-pending United States Patent Application Serial Number 09/721,088, filed November 22, 2000 as a continuation of United States Patent Application Serial Number 09/019,955, filed February 6, 1998 and** claims priority from United States Provisional Patent Application Serial Numbers 60/053,050 filed July 21, 1997, 60/045,184 filed April 30, 1997, and 60/037,325 filed February 7, 1997. The entire contents of each prior application is incorporated herein by reference.

In the claims:

Claims 1-40 are canceled, without prejudice.

New claims 41-60 are added.

Remarks

The priority application includes claims 1-40. As claims 1-40 have been canceled and claims 41-60 have been added, claims 41-60 are pending.

The new claims more clearly define the subject matter of the invention. No new matter is introduced.

Applicants respectfully request examination and consideration of claims 41-60.

Respectfully submitted,

Date: February 25, 2002

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